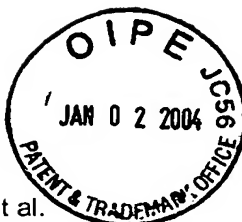


COMMISSIONER FOR PATENTS
P.O. Box 1450, Alexandria, VA 22313-1450



Docket No.: 300.1003CON
Date: December 30, 2003

In re application of: Chih-Ming CHEN, et al.
Serial No.: 10/603,254
Filed: June 25, 2003
For: **HMG-COA REDUCTASE INHIBITOR EXTENDED RELEASE FORMULATION**

Sir:

Transmitted herewith is an **Information Disclosure Statement** in the above-identified application.

- ☐ Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.
☐ Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.
☒ No fee for additional claims is required.
☐ A filing fee for additional claims calculated as shown below, is required:

FOR:	(Col. 1)	(Col. 2)		SMALL ENTITY		OR	LARGE ENTITY	
	REMAINING	HIGHEST		RATE	FEE		RATE	FEE
	AFTER	PREVIOUSLY	PRESENT					
	AMENDMENT	PAID FOR	EXTRA					
TOTAL CLAIMS	* Minus**	=	0	x \$	9		x \$	18
INDEP. CLAIMS	* Minus***	=	0	x \$	42		x \$	84
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				+	\$140		+	\$280

TOTAL: \$ OR TOTAL: \$

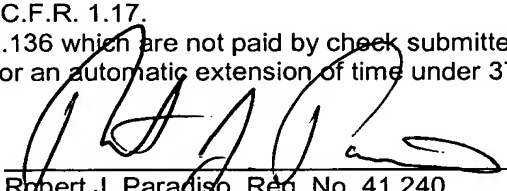
- * If the entry in Co. 1 is less than the entry in Col. 2, write "0" in Col. 3.
 ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
 *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

- ☒ Also transmitted herewith are:
☐ Petition for extension under 37 C.F.R. 1.136 (in duplicate)
☒ Other: **Form PTO-1449 form**

- ☐ Check(s) in the amount of **\$0.00** is/are attached to cover:
☐ Filing fee for additional claims under 37 C.F.R. 1.16
☐ Petition fee for extension under 37 C.F.R. 1.136
☐ Other:

- ☒ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.

- ☒ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
☒ Any patent application processing fees under 37 C.F.R. 1.17.
☒ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.


 Robert J. Paradiso, Reg. No. 41,240
 DAVIDSON, DAVIDSON & KAPPEL, LLC
 485 Seventh Avenue, 14th Floor
 New York, New York 10018
 Tel: (212) 736-1940
 Fax: (212) 736-2427

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with sufficient postage to the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on

December 30, 2003
 DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: 



300.1003CON

UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: To Be Assigned	Art Unit: 1614
Re: Application of:	Chih-Ming CHEN, et al.
Serial No.:	10/603,254
Filed:	June 25, 2003
For:	HMG-COA REDUCTASE INHIBITOR EXTENDED RELEASE FORMULATION

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

December 30, 2003

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R. § 1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

Pursuant to 37 C.F.R. § 1.98(d), copies of the references listed on the accompanying Form PTO-1449 (4 pages) are of record in the parent application (U.S. Patent Application No. 09/435,576) and are not enclosed. If it is determined that any of the listed references are not of record in the parent application, the Examiner is requested to contact the undersigned so that a copy can be forwarded.

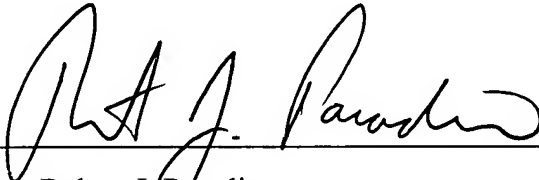
This Information Disclosure Statement and accompanying Form PTO-1449 are being filed under C.F.R. § 1.97(b)(3) before the mailing of a first Office Action. Accordingly, no fee is due. In the event any fee is due or overpayment made in connection with the filing of this

Information Disclosure Statement, the Assistant Commissioner is hereby authorized to charge said deficiency or credit overpayment to our Deposit Account No. 50-0552.

It is respectfully requested that the references cited on the accompanying Form PTO-1449 be considered and made of record.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 
Robert J. Paradiso
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940



FORM PTO-1449 (REV. 7-80)										U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE										ATTY. DOCKET NO. 300.1003CON					SERIAL NO. 10/603,254									
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)																									APPLICANTS Chih-Ming CHEN, et al.									
FILING DATE June 25, 2003																				GROUP 1614														
U.S. PATENT DOCUMENTS																																		
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		AJ		5		5		5		8		8		7		9		9/24/96		Chen et al.		424		480										
		AK		5		5		4		3		1		5		4		8/6/96		Rork et al.		424		473										
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		AL		9		7		1		1		8		7		9		3/26/98		WO		A61K		9/22										
		AM		9		6		1		9		2		0		1		6/27/96		WO		A61K		9/24										
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)																																		
		AN		Hatano, Harumi, et al., <u>Pharmaceutical Preparation Inform of Coated Capsule Releasable at Lower Part Digestive Tract</u> , <i>Caplus</i> , 1997:195672.																														
		AO		Cheng, Haiyung, et al., <u>Evaluation of Sustained/Controlled-Release dosage Forms of 3-Hydroxy-3-Methylglutaryl-Coenzyme A (HMG-CoA) Reductase Inhibitors in Dogs and Humans</u> , <i>Pharmaceutical Research</i> (1993), 10:1683-1687.																														
		AP		McClelland, Gregory A., et al., <u>Placement of 3-Hydroxy-3-Methylglutaryl-Coenzyme A (HMG-CoA) Reductase Inhibitor Efficacy Through Administration of a Controlled Porosity Osmotic Pump Dosage Form</u> , <i>Pharmaceutical Research</i> (1991), 8:873-876.																														
		AQ		Illingworth, D. Roger, et al., <u>Comparative Efficacy of Once Versus Twice Daily Mevinolin in the Therapy of Familial Hypercholesterolemia</u> , <i>Clinical Pharmacology Therapy</i> (1986), 40:338-343.																														
EXAMINER															DATE CONSIDERED																			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.																																		



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		BP		4		9		4		6		5		8		6		8/7/90		McClelland et al.		424		473										
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FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
300.1003CONSERIAL NO.
10/603,254

LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANTS
Chih-Ming CHEN, et al.FILING DATE
June 25, 2003GROUP
1614

U.S. PATENT DOCUMENTS

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	DC	5	8	9	7	9	1	0	4/27/99	Rosenberg et al.	427	2.14	
	DD	5	8	7	4	5	2	2	2/23/99	Figuly et al.	528	422	
	DE	5	2	1	1	9	5	1	5/18/93	Sparer et al.	424	426	
	DF	5	1	2	0	5	4	8	6/9/92	McClelland et al.	424	473	
	DG	4	9	9	7	6	5	8	3/5/91	Alberts et al.	424	473	
	DH	4	9	9	4	2	7	3	2/19/91	Zentner et al.	424	422	
	DI	5	9	1	6	5	9	5	6/29/99	Chen et al.	424	480	
	DJ	6	4	3	6	4	4	1	8/20/02	Sako et al.	424	488	
	DK												
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	DN												
	DO												
	DP												
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	DR												

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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

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EXAMINER

DATE CONSIDERED

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